Attorney's Docket No.: 3800002.00055 / 4804US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Szalay et al.

Art Unit : 1633

Serial No.: 10/516,785

Examiner: Burkhart, Michael D.

Filed : June 27, 2005

Conf. No. : 7336 Cust. No. : 77202

Title

: LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS

AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR

INFLAMED TISSUE

Mail Stop Petition

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

PETITION FOR CORRECTION OF INFORMATION DISCLOSURE STATEMENT CLASSIFICATION UNDER 37 CFR 1.181

Dear Sir:

Applicant respectfully submits this Petition under 37 CFR 1.181 to correct the misclassification of submitted Information Disclosure Statements.

Remarks begin on page 2 of this paper.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label Number: EM 315355785 US

Date of Deposit: January 07, 2011

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop Petition, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Christopher M. Ochs

Attorney's Docket No.: 3800002.00055 / 4804US Applicant: Szalay et al. Petition for Correction of Information Disclosure Statement Classification

Serial No.: 10/516,785

Filed : June 27, 2005

REMARKS

This Petition is submitted under 37 CFR 1.181 to request the correction of misclassified Information Disclosure Statements submitted in connection with the above-referenced application. Petitions submitted under 37 CFR 1.181 invoke the supervisory authority of the Director. Provided are this Petition under 37 CFR 1.181, an authorization to charge any fee due to Deposit Account No. 02-1818, and copies of five (5) misclassified Information Disclosure Statements.

Statement of Facts

Information Disclosure Statements were submitted in connection with the abovecaptioned application on November 8, 2007; January 29, 2008; August 29, 2008; September 29, 2009; and April 13, 2010. Each Information Disclosure Statement was prepared in accordance with 37 C.F.R 1.97 and 1.98. As required under 37 C.F.R 1.98, each Information Disclosure Statement contained 1) a list of all patents, publications, applications, or other information submitted for consideration by the Office, including a column that provides a space next to each document to be considered for the Examiner's initials, and a heading that clearly indicates that the list is an Information Disclosure Statement; and 2) legible copies of all items listed. The items either were in English or a translation was provided. Copies of the misclassified Information Disclosure Statements filed on November 8, 2007; January 29, 2008; August 29, 2008; September 29, 2009; and April 13, 2010 are attached.

The submitted Information Disclosure Statements included a tabular Form PTO-1449, which was classified as an "IDS," and a written disclosure of information. In each instance, the written disclosure of information was misclassified in PAIR as a "Transmittal Letter" (November 8, 2007, "Transmittal Letter" of 4 pages; January 29, 2008, "Transmittal Letter" of 3 pages; August 29, 2008, "Transmittal Letter" of 8 pages; September 29, 2009, "Transmittal Letter" of 4 pages; and April 13, 2010, "Transmittal Letter" of 3 pages). Consequently the information contained therein was not considered or reviewed by the Examiner. The written disclosure often contains information including the identification of English language translations of items listed on the Form PTO-1449, information regarding joint ownership and copending applications, and other information that is not amenable to a tabular format. Information Disclosure Statements not only provide documents, but also can include discussions material to such documents and descriptions of other relevant information.

Attorney's Docket No.: 3800002.00055 / 4804US Applicant: Szalay et al.

Serial No.: 10/516,785

: June 27, 2005 Filed

Petition for Correction of Information Disclosure Statement Classification

Accordingly, this Petition has been filed to request the reclassification of the Information Disclosure Statements. The Information Disclosure Statements submitted on November 8, 2007; January 29, 2008; August 29, 2008; September 29, 2009; and April 13, 2010 were filed in accordance with 37 C.F.R. 1.97-1.98 and should therefore be classified as Information Disclosure Statements.

Conclusion

Accordingly, correction of the classification in PAIR of the Information Disclosure Statements submitted on November 8, 2007; January 29, 2008; August 29, 2008; September 29, 2009; and April 13, 2010 in connection with the above-referenced application and consideration by the Examiner of the documents and information contained therein, respectfully is requested.

The Commissioner is hereby authorized to charge the fee for the petition any fees that may be due \boxtimes in connection with this paper or with this application during its entire pendency to Deposit Account No. 02-1818.

Respectfully submitted,

Attorney Docket No. 3800002.00055 / 4804US

Address all correspondence to: 77202

Stephanie Seidman

K&L Gates LLP

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San Diego, California 92130

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email: stephanie.seidman@klgates.com

Attorney's Docket No.: 17248-004US1 / 4804US



Applicant: Aladar A. Szalay et al.

Art Unit : 1636

Serial No.: 10/516,785

Examiner: Daniel M. Sullivan

Filed

: June 27, 2005

Customer No.: 20985 Confirm. No.: 7336

Title

: Light emitting microorganisms and cells for diagnosis and therapy of diseases

associated with wounded or inflamed tissue

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN **ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (4 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the requirements of 37 C.F.R. §1.98, the following documents are provided for consideration by the Examiner:

> CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 965983055 US Date of Deposit November 8, 2007 I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Stephanie Seidman

Attorney's Docket No.: 17248-004US1 / 4804US Supplemental Information Disclosure Statement

1) Examination Report, issued October 26, 2005, in connection with European Patent Application No. 02012552.2 (Attorney Docket No. 17248-004EP1/4804EP).

- 2) Examination Report, issued June 22, 2007, in connection with European Patent Application No. 03735553.4 (Attorney Docket No. 17248-004EP2/4804BEP), which is a national stage filing of International Patent Application No. PCT/EP03/05907.
- 3-4) Office Actions, issued June 13, 2006 and March 12, 2007, in connection with U.S. Patent Application Serial No. 10/849,664 (Attorney Docket No. 17248-004002/4804B).
- 5) Office Action, issued October 4, 2007, in connection with Canadian Patent Application No. 2,456,055 (Attorney Docket No. 17248-003CA1/4803CA).
- 6) "Definition of Tumor", MedicineNet.com, www.medterms.com/script/main/art.asp?articlekey=5863 (Accessed on May 30, 2007).

The instant application is a national stage filing of International Patent Application No. PCT/EP03/05907, which claims priority to European Patent Application No. 02012552.2.

The table below lists Documents 1-6 and includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	1	Examination Report, issued October 26, 2005, in connection with European Patent Application No. 02012552.2.
	2	Examination Report, issued June 22, 2007, in connection with European Patent Application No. 03735553.4
	3	Office Action, issued June 13, 2006, in connection with U.S. Patent Application Serial No. 10/849,664
	4	Office Actions, issued March 12, 2007, in connection with U.S. Patent Application Serial No. 10/849,664
	5	Office Action, issued October 4, 2007, in connection with Canadian Patent Application No. 2,456,055
	6	"Definition of Tumor", MedicineNet.com, www.medterms.com/script/main/art.asp?articlekey=5863 (Accessed on May 30, 2007)

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

Serial No.	Filing Date	Docket No.
11/529,662	09/27/06	17248-002003/4802C
11/796,028	04/25/07	17248-002004/4802D

Applicant : Szalay et al. Attorney's Docket No.: 17248-004US 1 / 4804US Serial No.: 10/516,785 Supplemental Information Disclosure Statement

Serial No.: 10/516,785 Filed: June 27, 2005

11/796,027	04/25/07	17248-002005/4802E
10/849,664	05/19/04	17248-004002/4804B
11/827,518	07/11/07	17248-012001/4812
11/975,088	10/16/07	17248-015001/4815
11/975,090	10/16/07	17248-016001/4816

<u>Serial No.</u>	Filing Date	Docket No.
PCT/US2007/15829	07/11/07	17248-012WO1/4812PC
PCT/US2007/22172	10/16/07	17248-015WO1/4815PC

Attention is directed to copending U.S. Patent Application Serial No. 10/849,664 filed May 19, 2004, which is a continuation of U.S. Patent Application Serial No. 10/163,763, filed June 5, 2002. The instant application and the copending application include claims directed to methods of detection/visualization of wounds, wounded tissues, inflammation sites and inflamed tissues. The inventive entity listed on the instant application differs from the inventive entity in the copending application. Applicant is reviewing inventorship.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submiffed,

Stephanie Seidman Reg. No. 33,779

Attorney's Docket No.: 17248-004US1 / 4804US

Address all correspondence to:

Stephanie Seidman Fish & Richardson P.C. 12390 El Camino Real San Diego, California 92130 Telephone: (858) 678-4777

Facsimile: (202) 626-7796 email: seidman@fr.com

Substitute Form PTO-1449 (MS) (fied)

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 17248-004US1/4804US Application No. 10/516,785

Information Disclosure Statement by Applicant (Use several sheets if necessary)

Applicant Aladar A. Szalay et al.

Aladar A. Sz Filing Date

June 27, 2005

Group Art Unit 1636

(37 CFR §1.98(b))

			U.S. Pate	ent Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2007/0212727	9/13/07	Szalay et al.	435	6	04/25/07
	AB	2007/0202572	8/30/07	Szalay et al.	435	69.1	04/25/07
	AC	2003/0103941	06/05/03	Crombleholme et al.	424	93.2	10/09/02
	AD	2007/0025981	02/01/07	Szalay et al.	424	130.1	09/27/06
	AE	6,106,826	08/22/00	Brandt et al.	424	93.2	12/17/97
	AF	6,503,703	01/07/03	Palese et al.	435	5	08/11/00

Examiner	Desig.	Document	Documents or Published Foreign Pate Publication Country or			Translation		
Initial	ID ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AG	WO 00/69448	11/23/00	WIPO				
	AH	WO 02/071062	09/12/02	WIPO				
	AI	WO 04/030631	4/15/04	WIPO				
	ΑĴ	WO 97/35997	10/02/97	WIPO				
	AK	WO 98/05274	2/12/98	WIPO				
	AL	WO 98/35695	08/20/98	WIPO				
	AM	WO 99/30648	06/24/99	WIPO				

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
	AN	Abe et al., "Peripheral blood fibrocytes: differentiation pathway and migration to wound sites," Journal of Immunology 166:7556-7562 (2001).
-	AO	Ballas et al., "Adult bone marrow stem cells for cell and gene therapies: implications for greater use." Journal of Cellular Biochemistry, Supplement 38:20-28 (2002).
	AP	Bonadio, J., "Genetic approaches to tissue repair," Annals of the New York Academy of Sciences 961:58-60 (2002).
	AQ	Bulte et al., "Magnetodendrimers allow endosomal magnetic labeling and in vivo tracking of stem cells," Nature Biotechnology, 19(12):1141-1147 (2001).
	AR	Burt et al., "Treatment of autoimmune disease by intense immunosuppressive conditioning and autologous hemotopoietic stem cell transplantation," Blood 92(10):3505-3514 (1998).
	·AS	Byun et al., "Myocardial injury-induced fibroblast proliferation facilitates retroviral-mediated gene transfer to the rat heart in vivo," Journal of Gene Medicine 2(1):2-10 (2000).
	AT	Chen, Y., "Orthopedic applications of gene therapy," Journal of Orthopaedic Science 6:199-207, (2000).

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	ot in conformance and not considered. Include copy of this form with
next communication to applicant.	Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449 U.S. Department of Commerce (Modified) Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets If necessary) U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement Aladar A. Szalay et al.

| Filing Date | Group Art Unit June 27, 2005 | 1636 | |

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	Document
Initial	ID	Chen et al., "Therapeutic benefit of intravenous administration of bone marrow stromal cells after
	AU	cerebral ischemia in rats." Stroke 32:1005-1011 (2001).
i	AV	Chernajovsky et al., "Fighting cancer with oncolytic viruses," BMJ: British Medical Journal 332(7534):170-172 (2006).
	AW	Costa, G., et al., "Adoptive immunotherapy of experimental autoimmune encephalomyelitis via T cell delivery of the IL-12 p40 subunit," Journal of Immunology, 167(4):2379-2387 (2001).
	AX	Crombleholme, T., "Adenoviral-mediated gene transfer in wound healing," Wound Repair and Regeneration 8(6):460-472, (2000).
	AY	Cupp, C. and D. Bloom, "Gene therapy, electroporation, and the future of wound-healing therapies," Earial Plastic Surgery 18(1):53-57 (2002).
	AZ	Deodato et al. "Recombinant AAV vector encoding human VEGF165 enhances wound healing" Gene Therapy 9:777-785 (2002)
	ВА	Eming, S., et al., "Gene therapy for tissue repair: approaches and prospects," British Journal of
	ВВ	Falk et al., "Improved adherence of genetically modified endothelial cells to small-diameter expanded polytetrafluoroethylene grafts in a canine model," Journal of Vascular Surgery 902-908.
	ВС	Fox et al., "Anaerobic bacteria as a delivery system for cancer gene therapy: in vitro activation of 5," Gene Therapy 3:173-178 (1996).
	BD	Fox et al., Erratum to "Anaerobic bacteria as a delivery system for cancer gene therapy: in vitro activation of 5," Gene Therapy 3:741 (1996).
	BE	Gautam et al., "Delivery systems for pulmonary gene therapy," American Journal of Respiratory Medicine 1(1):35-46 (2002).
	BF	Ghivizzani, S., et al., "Direct adenovirus-mediated gene transfer of interleukin 1 and tumor necrosis factor alpha soluble receptors to rabbit knees with experimental arthritis has local and distal anti-arthritic effects," Proceedings of the National Academy of Sciences of the United States of America 95(8):4613-4618 (1998)
	BG	Ghivizzani, S., et al., "Direct retrovirus-mediated gene transfer to the synovium of the rabbit knee: implications for arthritis gene therapy." Gene Therapy 4(9):977-982 (1997).
	вн	Gordon, E., et al., "Lesion-targeted injectable vectors for vascular restenosis," Human Gene Therapy, 12:1277-1287, (2001).
	BI	Gura, "Systems for identifying new drugs are often faulty," Science 278:1041-1042 (1997).
	ВЈ	Hall, F., et al., "Targeting retroviral vectors to vascular lesions by genetic engineering of the MoMLV gp70 envelope protein," Human Gene Therapy, 8:2183-2192, (1997).
	BK	Iwaguro et al., "Endothelial progenitor cell vascular endothelial growth factor gene transfer for vascular regeneration." Circulation 105:732-738 (2002).
	BL	Kelland et al. "Of mice and men: values and liabilities of the athymic nude mouse model in anticancer drug development." European Journal of Cancer 40:827-836 (2004).
	ВМ	Kerbel et al., "Human tumor xenografts as predictive preclinical models for anticancer drug activity in humans." Cancer Biology & Therapy 2:4 suppl. 1 S134-S139 (2003).
	BN	Kirn et al. "A tale of two trials: selectively replicating herpesviruses for brain tumors," Gene Therapy 7(10):815-816 (2000).
~	ВО	Kohler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," Nature 256:495-497 (1975).

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 17248-004US1/4804US Application No. 10/516,785

Information Disclosure Statement by Applicant (Use several sheets if necessary)

Applicant Aladar A. Szalay et al.

Filing Date Group Art Unit June 27, 2005 1636

(37 CFR §1.98(b))

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	Document
Initial	ID BP	Kotton et al., "Bone marrow-derived cells as progenitors of lung alveolar epithelium," Development 128:5181-5188 (2001).
	BQ	Larocca et al., "Gene transfer to mammalian cells using genetically targeted filamentous bacteriophage." FASEB Journal 13:727-734 (1999).
	BR	Lee et al., "Regeneration of hyaline cartilage by cell-mediated gene therapy using transforming growth factor beta 1-producing fibroblasts" Human Gene. Ther. 12(14):1805-1813 (2001).
	BS	Liechty, K., et al., "Adenoviral-mediated overexpression of platelet-derived growth factor-B corrects ischemic impaired wound healing," Journal of Investigative Dermatology 113(3):375-383 (1999).
	BT	Lindsey et al., "Modified cold virus kills colon cancer," Lancet Oncology 3(5):264 (2002).
	BU	Lock, C., et al., "The role of TNFalpha and lymphotoxin in demyelinating disease," Annals of the Rheumatic Diseases 58 Suppl 1:I121-I128 (1999).
	BV	Lutz et al., "Independent and tight regulation of transcriptional units in Escherichia coli via the LacR/O, the TetR/O and AraC/I1-I2 regulatory elements," Nucleic Acids Research 25:1203-1210 (1997).
	BW	Marti et al., "PBSC autotransplant for inflammatory bowel disease (IBD):a case of ulcerative colitis," Bone Marrow Transplantation 28:109-113 (2001).
	BX	McCluskie et al., "Route and Method of Delivery of DNA Vaccine Influence Immune Responses in Mice and Non-Human Primates" Mol. Med. 5:287-300 (1999)
	BY	Meuli, M., et al., "Efficient gene expression in skin wound sites following local plasmid injection," Journal of Investigative Dermatology 116(1):131-135 (2001).
	BZ	Moats et al., "A 'smart' magnetic resonance imaging agent that reports on specific enzymatic
	CA	Musso et al., "Crohn's disease complicated by relapsed extranodal Hodgkin's lymphoma: prolonged complete remission after unmanipulated PBPC autotransplant" Bone Marrow Transplantation 26:921-923 (2000)
	СВ	Okuma et al., "Reinsertion of stimulated nucleus pulposus cells retards intervertebral disk degeneration: an in vitro and in vivo experimental study," Journal of Orthopaedic Research 18(6):988-997 (2000).
	CC	Orlic et al., "Bone marrow cells regenerate infarcted myocardium," Nature 410:701-705 (2001).
	CD	Parikh et al., "Endothelial cell delivery for cardiovascular therapy," Advanced drug delivery reviews 42(1-2):139-161 (2000).
•	CE	Parks, E., et al., "Transient gene transfer of IL-12 regulates chemokine expression and disease severity in experimental arthritis." Journal of Immunology 160(9):4615-4619 (1998).
	CF	Pfeifer et al., "Gene Therapy: Promises and Problems," Annual Review of Genomics and Human Genetics 2:177-211 (2001).
	CG	Rosengart, T., et al., "Six-month assessment of a phase I trial of angiogenic gene therapy for the treatment of coronary artery disease using direct intramyocardial administration of an adenovirus vector expressing the VEGF121 cDNA," Annals of Surgery 230(4):466-470; discussion 470-472 (1999).
	СН	Rubanyi et al., "The future of human gene therapy," Molecular Aspects of Medicine 22:113-142 (2001).

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include copy of this form with
next communication to applicant.	Substitute Disclosure Form (PTO-1449)

Sheet <u>4</u> of <u>4</u>

Substitute Form PTO-1449 (Modified) Application No. U.S. Department of Commerce Attorney's Docket No. Patent and Trademark Office 10/516,785 17248-004US1/4804US **Applicant Information Disclosure Statement** Aladar A. Szalay et al. by Applicant (Use several sheets if necessary) Filing Date **Group Art Unit** June 27, 2005 1636 (37 CFR §1.98(b))

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
	CI	Schaffer, D., "Genetic approaches to tissue repair," Annals of the New York Academy of Sciences 961:68-70 (2002).
	CJ	Spencer, B., et al., "Herpes simplex virus-mediated gene delivery to the rodent visual system," Investigative Opthalmology & Visual Science 41(6):1392-1401 (2000).
	СК	Sugaya et al., "Stem cell strategies for neuroreplacement therapy in Alzheimer's disease," Medical Hypotheses 57(6):697-700 (2001).
	CL	Wahl et al., "Improved Radioimaging and Tumor localization with Monoclonal F(ab')2," Journal of Nuclear Medicine 24:316-325 (1983).
	СМ	Wedderburn et al., "Autologous stem cell transplantation for paediatric-onset polyarteritis nodosa: changes in autoimmune phenotype in the context of reduced diversity of the T- and B-cell repertoires, and evidence for reversion from the CD45RO+ to RA+ phenotype," Rheumatology 40:1299-1307 (2001).
	CN	Willenborg, D., "Cytokines and murine autoimmune encephalomyelitis: inhibition or enhancement of disease with antibodies to select cytokines, or by delivery of exogenous cytokines using a recombinant vaccinia virus system," Scandinavian Journal of Immunology 41(1):31-41 (1995).
	СО	Yang, W., et al., "sFlt-1 gene-transfected fibroblasts: a wound-specific gene therapy inhibits local cancer recurrence," Cancer Research 61(21):7840-7845 (2001).

Examiner Signature	Date Considered
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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Attorney's Docket No.: 17248-004US1 / 4804US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

olicant: Aladar A. Szalay et al.

Art Unit : 1636

Serial No.: 10/516,785 Filed

: June 27, 2005

Examiner: Daniel M. Sullivan

Customer No.: 20985 Confirm. No.: 7336

· Title

: Light emitting microorganisms and cells for diagnosis and therapy of diseases

associated with wounded or inflamed tissue

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN **ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (1 page) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of item noted below. Item AC (Fu et al.) is in the Chinese language and an English language translation is provided (Item AD). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the requirements of 37 C.F.R. §1.98, the following documents are provided for consideration by the Examiner:

> CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 965985811 US Date of Deposit January 29, 2008

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the data indicated above and is addressed to: Commissioner for Patents U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria 14, 22313-1450.

Attorney's Docket No.: 17248-004US1 / 4804US Supplemental Information Disclosure Statement

1) Office Action, issued November 28, 2007, in connection with U.S. Patent Application Serial No. 10/849,664 (Attorney Docket No. 17248-004002/4804B).

The table below lists Document 1 and includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document	
		Office Action, issued November 28, 2007, in connection with U.S. Patent Application Serial No. 10/849,664	

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

Serial No.	Filing Date	Docket No.
11/982,102	10/31/07	17248-003003/4803C
11/982,040	10/31/07	17248-003004/4803D
11/981,976	10/31/07	17248-003005/4803E
11/982.035	10/31/07	17248-003006/4803F

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman

Attorney's Docket No.: 17248-004US1 / 4804US

Address all correspondence to:

Stephanie Seidman Fish & Richardson P.C. 12390 El Camino Real San Diego, California 92130 Telephone: (858) 678-4777

Facsimile: (202) 626-7796 email: seidman@fr.com

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Sheet <u>1</u> of <u>1</u>	
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Substitute 5 m PTO-1449 (Modified

U.S. Department of Commerce Patent and Trademark Office

Information Disclosure Statement

by Applicant (Use several sheets if necessary)

Attorney's Docket No. 17248-004US1/4804US

Application No. 10/516,785

Applicant

Aladar A. Szalay et al.

Filing Date

Group Art Unit

(37 CFR §1.98(b))

June 27, 2005

1636

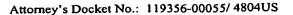
U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,833,975	11/10/98	Paoletti et al.	424	93.2	01/19/94

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Trans Yes	lation No
		none						

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	
Initial	ID	Document
	AB	Contag et al., "Visualizing Gene Expression in Living Mammals Using a Bioluminescent Reporter," Photochemistry and Photobiology 66(4):523-531 (1997).
	AC	Fu et al., "Relationship between gut origin bacteria and wound infection after thermal injury," Zhonghua Wai Ke Za Zhi 32(10):615-618 (1994).
	AD	English Translation of Fu et al., "Relationship between gut origin bacteria and wound infection after thermal injury," from the Chinese, Zhonghua Wai Ke Za Zhi 32(10):615-618 (1994).
	AE	Gelfand et al., "Infections in burn patients: a paradigm for cutaneous infection in the patient as risk," American Journal of Medicine 76(5A):158-165 (1984).
	AF	Huang et al., "Bacterial penetration across the blood-brain barrier during the development of neonatal meningitis," Microbes and Infection 2(10):1237-1244 (2000).
	AG	Lu et al., "Delivery of adenoviral vectors to the prostate for gene therapy," Cancer Gene Therapy 6(1):64-72 (1999).
	АН	Perkus et al., "Deletion of 55 open reading frames from the termini of vaccinia virus," Virology 180:406-410 (1991).
	AI	Weissleder et al., "In vivo imaging of tumors with protease-activated near-infrared fluorescent probes," Nature Biotechnology 17:375-378 (1999).
	AJ	Weng et al., "HO-1 expression in type II pneumocytes after transpulmonary gene delivery," American Journal of Physiology. Lung Cellular and Molecular Physiology 278:L1273-L1279 (2000).

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include copy of this form with
next communication to applicant.	O Luth to Displaces Form (DTO 4449)

Substitute Disclosure Form (PTO-1449)





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar A. Szalay et al.

Serial No.: 10/516,785

Filed

: June 27, 2005

Art Unit: 1636

Examiner: Daniel M. Sullivan

Customer No.: 77202 Confirm. No.: 7336

Title

: Light emitting microorganisms and cells for diagnosis and therapy of diseases

associated with wounded or inflamed tissue

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN **ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (1 page) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item AE (JP 09-502993) is in the Japanese language and an English language equivalent (AU 709336) is provided (Item AF). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, this Supplemental Information

> CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EM 247738050 US Date of Deposit August 29, 2008

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Kethya Teuk

Attorney's Docket No.: 0119356-00055/ 4804US Supplemental Information Disclosure Statement

Applicant: Szalay et al. Serial No.: 10/516,785 Filed: June 27, 2005

Disclosure Statement (sIDS) includes a table listing Office Actions cited in related and corresponding U.S. and foreign Patent Applications, and other documents (Documents 1-3). In accordance with the requirements of 37 C.F.R. 1.98, the following documents are listed for consideration by the Examiner:

- 1) Examination Report, issued January 30, 2008, in connection with European Patent Application No. 02012552.2 (Attorney Docket No. 0119356-00059/4804EP).
- 2) Examination Report, issued February 1, 2008 (with English translation), in connection with corresponding Chinese Patent Application No. 03812787.3 (Attorney Docket No. 0119356-00058/4804CN), which is a national stage filing of International Patent Application No. PCT/EP03/05907. The instant application is a national stage filing of the same International Patent Application No. PCT/EP03/05907.
- 3) Office Action, issued March 18, 2008, in connection with U.S. Patent Application Serial No. 10/866,606 (Attorney Docket No. 0119356-00023/4803B).

The table below lists Documents 1-3 and includes a column that provides a space next to the document to be considered, for the Examiner's initials. This Information Disclosure Statement (IDS) includes the application number of the application in which the IDS is being submitted, a column that provides a blank space next to each citation for the Examiner's initials, a heading on the listing that clearly indicates the list is an Information Disclosure Statement, and copies of Documents 1-3. Therefore, this sIDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant respectfully requests that Examiner consider and initial all information listed in the table below.

Examiner Initial	Document No.	Document		
	1	Examination Report, issued January 30, 2008, in connection with European Patent Application No. 02012552.2		
	2	Examination Report, issued February 1, 2008, in connection with corresponding Chinese Patent Application No. 03812787.3		
	3	Office Action, issued March 18, 2008, in connection with U.S. Patent Application Serial No. 10/866,606		

In the Office Action dated January 28, 2008, the Examiner initialed and returned Forms PTO-1449 from the Information Disclosure Statement (IDS) submitted on November 8, 2007. The IDS filed on November 8, 2007 contained a Table listing Office Actions cited in related and corresponding U.S. and foreign Patent Applications, and other documents (Documents 1-6). This Table was **not** initialed by the Examiner. The IDS submitted

Attorney's Docket No.: 0119356-00055/4804US Supplemental Information Disclosure Statement

November 8, 2007 included the application number of the application in which the IDS was being submitted, a column that provides a blank space next to each citation for the Examiner's initials, a heading on the listing that clearly indicates the list is an Information Disclosure Statement, and copies of listed documents. Therefore, the November 8, 2007 IDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant respectfully requests that Examiner consider and initial all information listed in the table submitted in the IDS filed November 8, 2007.

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

Serial No.	Filing Date	Docket No.
US 12/148,542	04/17/08	0119356-00126/ 4802F
US 12/080,766	04/04/08	0119356-00127/ 4816B
US 12/156,135	05/30/08	0119356-00128/4817
PCT/US2008006917	05/30/08	0119356-00129/4817PC
US 157,960	06/13/08	0119356-00131/112
PCT/US2008/07377	06/13/08	0119356-00132/112PC

Inventorship

The instant application and U.S. Patent Application Serial No. 10/849,664 (Attorney Docket No. 0119356-00054/4804B) (the '664 application), filed May 19, 2004, now abandoned, include claims directed to methods of detection/visualization of wounds, wounded tissues, inflammation sites and inflamed tissues, by administering microorganisms. The inventive entity listed on the '664 application differs from the inventive entity listed on the instant application. The inventive entity listed on the '664 application as originally filed is Dr. Aladar Szalay and Dr. Douglas A. Will. The inventive entity listed on the instant application as originally filed is Dr. Szalay, Dr. Shahrokh Shabahang, and Dr. Yong A. Yu. Since the '664 application and the instant application have very similar specifications and some overlapping claims, but different inventive entities, a review to confirm inventorship of the instant application was conducted.

To review inventorship of the instant application, discussions were conducted with Dr. Szalay and Dr. Yu and Dr. James Chang, in-house counsel for Genelux Corporation. In addition, Chang conducted a review of Genelux records and had further discussions with

Attorney's Docket No.: 0119356-00055/4804US Supplemental Information Disclosure Statement

named inventors Szalay and Yu. Drs. Szalay and Yu confirmed that Szalay, Yu and Shabahang contributed to inventorship of the instant application. None of Genelux's company records, discussions with the named inventors Szalay and Yu by Chang, or discussions with Dr. Szalay, current CEO, revealed any contributions of Dr. Will to conception of any claim in the instant application as originally filed or currently pending.

Dr. Will was named on the '664 application, but is not named on the instant application. Dr. Will was a founder of Genelux in September 2001, and was the first member of the Board of Directors and became President of the Corporation in October 2001. In January 2002, Dr. Will became Chief Executive Officer (CEO). In April 2003, Dr. Will resigned from the Board of Directors and his employment as President and CEO was terminated for cause by the Board. During the time period between September 2001 and April 2003 the European application EP 02012552.2, to which the instant application ultimately claims priority, and U.S. Patent Application Serial No. 10/163,763, which is the parent of the '664 application, were filed. The inventive entity on the European application EP 02012552.2 was Dr. Szalay and the inventive entity on U.S. Patent Application Serial No. 10/163,763 is the same as the inventive entity on the '664 application. The instant application and the '664 application were filed after April 2003.

Letters were sent to Dr. Will to schedule a discussion regarding inventorship and/or to provide any evidence in his possession of his inventive contribution. Dr. Will did not provide any evidence of his inventive contribution and requested payment of \$15,000 for any discussion, which the company declined to pay. As noted above, the review of inventorship confirmed that Drs. Szalay, Yu and Shabahang contributed to inventorship of the instant application. In view of the fact that none of the other inventors recalled any contribution by Dr. Will to the instant application, and no company records revealed any contribution, it was concluded that the inventive entity is correctly named in the instant application.

Although these documents and information are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a

Attorney's Docket No.: 0119356-00055/4804US Supplemental Information Disclosure Statement

search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seleman Reg. No. 33,779

Attorney's Docket No.: 119356-00055/ 4804US

Address all correspondence to: 77202
Stephanie Seidman
Bell, Boyd & Lloyd LLP
3580 Carmel Mountain Road, Suite 200
San Diego, California 92130

Telephone: (858) 509-7410 Facsimile: (858) 509-7460 email: sseidman@bellboyd.com

Sheet	1	of	1

Substitute Form PTO-144	9
(Modified)	
8 1 4 Information	- D:

U.S. Department of Commerce Patent and Trademark Office

Attorney's Docket No. 119356-00055/4804US Application No. 10/516,785

Information Disclosure Statement by Applicant
(Use several sheets if necessary)

Applicant Aladar A. Szalay et al.

Filing Date

June 27, 2005

Group Art Unit 1636

RADE	U.S. Patent Doc			nt Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2005/0025745	02/03/05	Fujimori et al.	424	93.2	02/23/04

Examiner	Desig.	Document	Publication	Country or			Trans	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AB	WO 04/069178	08/19/04	WIPO				
	AC	WO 00/23471	04/27/00	WIPO				
	AD	WO 00/71718	11/30/00	WIPO				
	AE	JP 09-502993	03/25/97	JР				х•
<u> </u>	AF	AU 709336	04/18/95	AU				

		Other Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	Document
Initial	ID_	
	AG	Demkowicz et al., "Human Cytotoxic T-Cell Memory: Long-Lived Responses to Vaccinia Virus," J. Virol. 70(4):2627-2631 (1996).
	AH	Lopez-Guerrero et al., "Therapeutic Effect of Recombinant Vaccinia Virus Expressing the 60-kd Heat Shock Protein on Adjuvant Arthritis," Arthr Rheum 37(10):1462-1467 (1994).
	AI	Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy." (1995).
	AJ	Stienlauf et al., "Kinetics of formation of neutralizing antibodies against vaccinia virus following revaccination," Vaccine 17:201-204 (1999).

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Attorney's Docket No.: 3800002.00055/ 4804US

ITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar A. Szalay et al.

: 1633 Art Unit Examiner: Michael D. Burkhart

Serial No.: 10/516,785 Customer No.: 77202

: June 27, 2005 Filed Confirm. No.: 7336

Title

: LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS

AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR

INFLAMED TISSUE

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (2 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item AR (JP2000-502884) is in the Japanese language and an English equivalent (WO 97/18841) was provided in the Information Disclosure Statement filed April 18, 2006 (Item BM); Item AQ (JP2000-295987) is in the Japanese language and includes an English language translation and is provided with a Derwent Abstract (Item AY); Item BA (Japanese Journal of Clinical and Experimental Medicine) is in the Japanese language and includes a certified English translation of the abstract and summary (Item AX);

10516785 00000019 021818 10/02/2009 JADDO1

189.99 DA 01 FC:1886

CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EM 315453544 US Date of Deposit September 29, 2009 I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Mexandria, Y 522313 435.

Attorney's Docket No.: 3800002.00055/4804US Supplemental Information Disclosure Statement

Item BE (Sumii et al.) is in the Japanese language and includes an English language abstract on the last page of the article. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

Docket No.	Application No.	Filing Date
3800002.00074/4812B	12/008,659	01/11/08
3800002.00135/113	12/218,953	07/18/08
3800002.00136/113PC	PCT/US2008/008882	07/18/08
3800002.00144/117	12/288,887	10/24/08
3800002.00145/117PC	PCT/US2008/12061	10/24/08
3800002.00148/4819	12/319,640	01/09/09
3800002.00149/4819PC	PCT/US2009/00148	01/09/09
3800002.00155/4802G	12/462,074	07/28/09

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, this Supplemental Information Disclosure Statement (sIDS) includes Office actions cited in related U.S. Patent Applications, and other documents:

- 1) Office Action, issued December 3, 2008, in connection with Israeli Patent Application No. 165350 (Attorney Docket No. 3800002.062/4804IL), which is a national stage filing of International Patent Application No. PCT/EP03/05907. The instant application is a national stage filing of International Patent Application No. PCT/EP03/05907.
- 2) Office Action, issued January 27, 2009, in connection with Japanese Patent Application No. 2004-511544 (Attorney Docket No. 3800002.065/4804JP), which is a national stage filing of International Patent Application No. PCT/EP03/05907. The instant application is a national stage filing of International Patent Application No. PCT/EP03/05907.
- 3) Office Action, issued March 30, 2009, in connection with Canadian Patent Application No. 2,488,227 (Attorney Docket No. 3800002.00057/4804CA), which is a national stage filing of International Patent Application No. PCT/EP03/05907. The instant application is a national stage filing of International Patent Application No. PCT/EP03/05907.

Attorney's Docket No.: 3800002.00055/4804US Supplemental Information Disclosure Statement

4) Office Action, issued June 26, 2009, in connection with Chinese Patent Application No. 03812787.3 (Attorney Docket No. 3800002.00058/4804CN), which is a national stage filing of International Patent Application No. PCT/EP03/05907. The instant application is a national stage filing of International Patent Application No. PCT/EP03/05907.

The table below lists Documents 1-8 and includes a column that provides a space next to each document to be considered, for the Examiner's initials. The documents cited on the table below are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary. This sIDS includes the application number of the application in which the sIDS is being submitted, a heading that clearly indicates the list is an Information Disclosure Statement, and copies of Documents 1-8. Therefore, this sIDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant respectfully requests that Examiner consider and initial all information listed in the table below.

Examiner Initial	Document No.	Document
	1	Official Action, issued December 3, 2008, in connection with Israeli Patent Application No. 165350.
	2	Official Action, issued January 27, 2009, in connection with Japanese Patent Application No. 2004-511544.
	3	Official Action, issued March 30, 2009, in connection with Canadian Patent
	4	Official Action, issued June 26, 2009, in connection with Chinese Patent Application No. 03812787.3.
	5	Amato et al., "Luminous with Promise", Chem. Eng. News. 84(49):69-73
	6	Loessner et al., "Remote control of tumour-targeted Salmonella enterica serovar Typhimurium by the use of L-arabinose as inducer of bacterial gene expression in vivo", Cell. Microbiol. 9(6):1529-1537 (2007).
	7	Loessner et al., "Drug-inducible remote control of gene expression by probiotic Escherichia coli Nissle 1917 in intestine, tumor and gall bladder of mice". Microb. Infect. Published online: 7 August 2009.
······································	8	Westphal et al., "Containment of tumor-colonizing bacteria by host neutrophils", Cancer Res. 68(8):2952-2960.

Although these documents and information are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a

Attorney's Docket No.: 3800002.00055/ 4804US Supplemental Information Disclosure Statement

search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman Reg No. 33,779

Attorney's Docket No.: 3800002.00055/ 4804US

Address all correspondence to: 77202

Stephanie Seidman K&L Gates LLP 3580 Carmel Mountain Road, Suite 200

San Diego, California 92130 Telephone: (858) 509-7410 Facsimile: (858) 509-7460

email: stephanie.seidman@klgates.com

Substitute Form PTO-144 (Modified)

rtment of Commerce and Trademark Office Attorney's Docket No. 3800002.00055/4804US Application No. 10/516,785

Information Disclosure Statement

by Applicant (Use several sheets if necessary) Applicant Szalay et al.

Filing Date June 27, 2005 **Group Art Unit** 1633

(37 CFR §1.98(b))

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2008/0193373	08/14/08	Stritzker et al.	424	1.17	07/11/07
	AB	2009/0081639	03/26/09	Hill et al.	435	5	05/30/08
	AC	2009/0117047	05/07/09	Szalay et al.	424	9.3	10/31/07
	AD	2009/0117048	05/07/09	Szalay et al.	424	9.3	10/31/07
	AE	2009/0117049	05/07/09	Szalay et al.	424	9.3	10/31/07
	AF	2009/0123382	05/14/09	Szalay et al.	424	9.6	10/31/07
	AG	2009/0136917	05/28/09	Szalay et al.	435	5	10/24/08
	AH	2009/0155287	06/18/09	Chen et al.	424	158.1	04/04/08
	AI	2009/0162288	06/25/09	Chen et al.	424	9.3	07/18/08
	AJ	2009/0180955	07/16/09	Stritzker et al.	424	1.73	01/09/09
	AK	2009/0180987	07/16/09	Stritzker et al.	424	93.2	01/11/08
	AL	6,150,170	11/21/00	Powell et al.	435	455	07/30/98
	AM	6,916,462	07/12/05	Contag et al.	424	9.6	02/16/95
	AN	7,588,767	09/15/09	Szalay et al.	424	199.1	06/18/04
	AO	7,588,771	09/15/09	Szalay et al.	424	232.1	09/27/05

		Foreign Patent	Documents or Pu	blished Foreign Pate	nt Applicat	ions	,	
Examiner	Desig.	Document	Publication	Country or	01	Subclass		lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
-	AP	EP 1489164	12/22/04	EP				
	AQ	JP 2000-295987	10/24/00	JР				*
	AR	JP 2000-502884	03/14/00	JP			+	
	AS	WO 84/00381	02/02/84	WIPO				
	AT	WO 89/11294	11/30/89	WIPO				
	AU	WO 01/48231	07/05/01	WIPO				
	AV	WO 08/099001	08/21/08	WIPO				
	AW	WO 08/100292	05/14/09	WIPO				

^{* =} English language equivalent provided.

^{+ =} English language translation and is provided with a Derwent English Abstract.

Г			Other Documents (include Author, Title, Date, and Place of Publication)
ł	Examiner	Desig.	Other Bookinetto (instance) that a say that
1	Initial	ID	Document

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office		Attomey's Docket No. 0119356-	Application No. 10/516,785			
le.	formation	n Disclosure Statement	00055/4804US			
111		by Applicant	Applicant			
		veral sheets if necessary)	Aladar A. Szalay et al.			
	•	••	Filing Date	Group Art Unit		
(37 CFR §1.98	3(b))	· ·	June 27, 2005	1636		
		Certified English language translation		panese Journal of Clinical and		
	Experimental Medicine 66:1877-188) (1989).			
		Derwent English Abstract for Japanes	se Patent Publication JP 2000295	987, published October 24,		
	AY	2000, entitled, "Transdifferentiation of Transfected Epidermal Basal Cell Into Neutral Progenitor				
		Cell, Neuronal Cell and/or Glial Cell," (9 pages) Derwent Accession Number: 10188304.				
	4.7	Hermiston, T and D. Kirn, "Genetically based therapeutics for cancer: similarities and contrasts with				
	AZ	traditional drug discovery and development," Mol. Ther. 11(4):496-507 (2005).				
	BA	Japanese Journal of Clinical and Expe				
	BB	Kruis W., "Review article: antibiotics and probiotics in inflammatory bowel disease," Pharmacol.				
	БВ	Ther. 20 (Suppl 4): 75-78 (2004). Meighen et al., "Molecular Biology of Bacterial Bioluminescence", Microbiological Reviews				
	ВС		f Bacterial Bioluminescence", N	iicrobiological Keviews		
		55(1):123-142 (1991).		4 allows real time		
	BD	Riedel et al., "Improved luciferase tagging system for listeria monocytogenes allows real-time monitoring in vivo and in vitro," Appl. Environ. Microbiol. 73:3091-3094 (2007).				
	I monitoring in vivo and in vitro." ADD		1. Environ. Microbiol. /3:3091-	tient " Journal of the Jananese		
	22	Sumii et al., "A Case of salmonella pr Association for Infectious Diseases 60	rostautis in a renai transpiant pat n.624_626 (1986). Fin Tananece 1	anguage with English language		
	BE	Association for Infectious Diseases of summary]	0.024-020 (1900). [III Japanese 1	mibanba wini mibini imibanba		
	DE DE	Taubes et al., "Firefly gene lights up l	ab animals inside out " Science	276(5321):1993 (1997).		
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Examiner Signature	Date Considered
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Attorney's Docket No.: 3800002.00055/ 4804US

N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar A. Szalay et al.

Art Unit : 1633

Serial No.: 10/516,785

Examiner: Michael D. Burkhart

Cust. No. : 77202 Filed : June 27, 2005

Conf. No. : 7336

Title

: LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR

INFLAMED TISSUE

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (1 page) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of the item noted below. Item AD (DE 44 25 382) is in the German language and a Certified English translation is provided (Item AF). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

> CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EM 315456381 US. Date of Deposit April 13, 2010 I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

> > Jon Levy

Attorney's Docket No.: 3800002.00055/ 4804US Supplemental Information Disclosure Statement

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, this Supplemental Information Disclosure Statement (sIDS) includes a Search Report and Written Opinion, issued September 22, 2009, in connection with a corresponding International application, Singapore Patent Application No. 200701613-2 (Attorney Docket No. 3800002.00068/4804BSG).

The table below includes a column providing a space for the Examiner's initials next to the document to be considered. The document cited on the table below is in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed item is necessary. This sIDS includes the application number of the application in which the sIDS is being submitted, a heading that clearly indicates the list is a Supplemental Information Disclosure Statement, and a copy of the document listed below. Therefore, this sIDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant respectfully requests that Examiner consider and initial all information listed in the table below.

Examiner Initial	. Document
	Search Report and Written Opinion, issued September 22, 2009, in connection with Singapore Patent Application No. 200701613-2.

Although these documents and information are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Attorney's Docket No.: 3800002.00055/4804US Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman Reg. No. 33,779

Attorney's Docket No.: 3800002.00055/ 4804US

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email: stephanie.seidman@klgates.com

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U.S. Department of Commerce Patent and Trademark Office

Attorney's Docket No. 3800002.00055/4804US Application No. 10/516,785

tion Disclosure Statement by Applicant several sheets if necessary)

Applicant

Szalay et al. Filing Date

Group Art Unit 1633

June 27, 2005

HAND			U.S. Paten	t Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	7,662,398	02/16/10	Szalay et al.	424	232.1	9/27/06
	AB	2010/0008946	01/14/10	Szalay et al.	424	199.1	7/28/09
	AC	2010/0062016	03/11/10	Szalay et al.	424	199.1	10/26/09

Examiner	Desig.	Document	Publication	blished Foreign Pa			Trans	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AD	44 25 382	8/14/97	DE			X+	
	AE	WO 09/126189	10/15/09	WIPO				

Other Documents (include Author, Title, Date, and Place of Publication)						
Examiner Initial	Desig. ID	Document				
	AF	Certified English translation of DE 44 25 382 A1, published January 25, 1996, entitled: "Method for detection of live bacterial vectors." [Patent in German].				

Date Considered Examiner Signature

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.